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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,642	SCHAFFNER, I. RICHARD	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *12 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment to the claims filed on 8 August 2005, does not comply with the requirements of 37 CFR 1.121(c) because the claim listing does not contain a listing of all the claims ever presented for examination in this case, as well as their status. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states (emphasis added):

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. ***In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).***

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

As noted above, the amendment under consideration herein fails to comply with 37 CFR 1.121 because the claim listing does not contain a listing of all the claims ever presented for examination in this case, as well as their status. Thus, the amendment could be considered non-responsive. However, in the interest of compact prosecution the amendment at issue will not be considered non-responsive. However, any future responses failing to comply with 37 CFR 1.121 will be held non-responsive, and will not be considered.

Status of Application

Applicant's arguments filed 8 August 2005 have been fully considered but they are not persuasive. Amendments to claims 11, 12, and 13 have been entered. Claims 1-18 remain pending in the current application.

Double Patenting

Applicant is advised that should claims 2 or 17 be found allowable, the other claim (either 2 or 17) will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case both claims are directed to a composition comprising lactose and Brewer's Yeast, wherein the lactose comprises approximately 40% to 85% by weight of said biological stimulant, and wherein said biological stimulant acts as an electron donor in said reductive dehalogenation. Though claim 2 describes the composition as

a biological stimulant for use in bioremediation via enhanced reductive dehalogenation and claim 17 describes the composition as a reductive dehalogenation composition, the compositions appear to be identical.

Claim Objections

Claims 12 and 17 are objected to because of the following informalities, neither of which were so grave as to render the claim indefinite (See 37 C.F.R. 1.75(d)(1) and MPEP §608.01(o)):

Claim 12 recites the limitation "said biological stimulant" in the 5th line of the claim. There is insufficient antecedent basis for this limitation in the claim; it is clear the should refer to the "said reductive dehalogenation composition."

Claim 17 recites the limitation "said lactose" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim; it is clear the claim should depend from claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims are directed to a reductive dehalogenation composition, comprising a biodegradable sugar; and Brewer's Yeast, wherein said biological stimulant acts as an electron donor in said biological stimulant acts as an electron donor in said reductive dehalogenation.

It is not clear what is meant by a "reductive dehalogenation composition;" it is not clear if the composition comprises chemicals capable of inducing reductive dehalogenation of halogenated

compounds, or if the composition comprises donor electrons that are directly responsible for reductive dehalogenation, or if the composition comprises chemicals which have been dehalogenated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, and 12-14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rebhan (US Patent 5,756,132).

Rebhan teaches a dry, water-dispersible milk replacement for calves comprising brewer's yeast, dextrose, lactose, lard and vegetable fats (which applicant calls fatty acids and vegetable oils) (See col. 2, ln 40-57) (Claims 1, 5-7, and 12-14). Though Rebhan does not teach the milk replacement as a biological stimulant for use in bioremediation, the composition comprises the same ingredients as claimed in the current application, and therefore inherently has the same electron donor properties as the claimed biological stimulant without evidence to the contrary. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, see *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Please note that if the body of claim fully and intrinsically sets forth all limitations of the claimed invention, such as all the components of a composition, and the preamble merely states the intended use of the invention, rather than any distinct definition of the any of the claimed invention's limitations, the preamble is not considered a limitation and is of no significance to claim construction. See MPEP § 2111.02. Therefore the reference anticipates the claimed subject matter.

Response to Arguments

Applicant argues that the examiner's incorrectly equated "lard and vegetable fats" (included in the composition of Rebhan) to "fatty acids and vegetable oils" (included in the present application). Applicants argue that their composition does not comprise any lard. Applicant further argues that the rejection based on inherent properties of the composition, not taking into account the intended use recited in the preamble, is improper. Applicant argues the case law of Jansen is more applicable than Pitney Bowes, as was relied on by the examiner. Applicants state that the preamble of the claims does not merely state the intended use, but rather requires the composition to be used in a specific set of chemical reaction methods- enhanced reductive dehalogenation, and specifies the method- electron donation. Applicants state that the composition of Rebhan is not capable of performing reductive dehalogenation. Finally, applicants argue that the examiner has not provided rationale or evidence tending to show inherency.

Applicant's arguments are not found persuasive. In response to applicant's argument that the inclusion of "lard and vegetable fats" in Rebhan's composition does not equate "fatty acids and vegetable oils" (included in the present invention), it is noted that applicants have submitted that "fatty acids are components of fats" (Response, paragraph bridging pages 6-7); therefore, because Rebhan's composition comprises fat, it also comprises fatty acids. The present claims do not teach the fatty acids must be included in a purified form; thus because the composition of Rebhan comprises lard and vegetable fats, it also inherently comprises fatty acids and vegetable oils.

In response to applicant's arguments regarding consideration of the preamble, it is noted that the fact pattern of the case cited by the applicant (*Jansen v Rexall Sundown, Inc*) and the fact pattern of the instant rejection are significantly different, and the court decision is not binding with regard to the instant rejection. Particularly, the Jansen case focused on the patentability of claims directed to a method of

treating macrocytic-magalobastic anemia, wherein the preamble limited the population of patients that the method was applicable to; the claims were not directed to the pharmaceutical product, per se. In Jansen the preamble was found to critical as it limited and directed the claimed method. However, in the present application the claims are not drawn to a method of enhancing reductive dehalogenation, but are drawn to the biological stimulant product; the preamble merely states the intended use and inherent properties of the composition. The preamble is denied the effect of a limitation where the claim or count, apart from the introductory clause, completely defines the subject matter of the invention, and the preamble merely states a purpose or intended use of that subject matter, See, *Kropa v Robie*, 187 F.2d 150, 88USPQ 478 (CCPA 1951) and *Bell Communications Research, Inc v Vitalink Communications Corp*, 55 F.3d 615, 620, 34 USPQ 2d, 1816, 182 (Fed. Cir. 1995). Therefore, because the body of the claim fully describes the composition, and the preamble is only relied on to state intended use and inherent properties, it does not impart limitation on the claimed composition. Thus, because the composition of Rebhan has the same composition as the currently claimed invention (comprising brewer's yeast, dextrose, lactose, lard and vegetable fats (which applicant calls fatty acids and vegetable oils)), the claimed and prior art products are identical in structure or composition and a prima facie case of either anticipation has been established, see *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Finally, in response to applicant's argument that the examiner has not provided motivation or rationale tending to show inherency, it is noted that such rationale is only required when the product of the prior art *appears* to be *substantially* identical to the currently claimed invention, when the prior art reference does not explicitly teach every claimed detail. However, in the instant case Rebhan teaches a composition comprising the exact claimed composition; thus because products of identical chemical composition can not have mutually exclusive properties rationale is not needed, the products are one and the same, see *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden is shifted

to applicant to show that the composition of the prior art is not capable of performing the reductive dehalogenation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 12-13 and 17-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Keasling et al (US Patent 6,150,157).

Keasling et al teach a biological stimulant composition for the reductive dehalogenation of organic halides in contaminated groundwater comprising a carbohydrate and a reductive dehalogenation factor in the form of a nutrient extract (See col. 2, ln 52-65). The carbohydrate can be lactose, sucrose or glucose (which applicant refers to as dextrose) (See col. 4, ln 9-22). The reductive dehalogenation factor can be yeast extracts (See col. 4, ln 40-67).

Though Keasling et al teach using yeast extracts, and not whole Brewer's yeast, as in the current application, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use whole yeast cultures instead of yeast extracts in order to reduce processing steps and costs. One of ordinary skill in the art would have been motivated to use whole yeast cultures, especially cultures of *Saccharomyces*, because such cultures are readily commercially available; plus by using whole cultures, instead of extracts, one saves the step of lysing the cells and separating out the desired extracts. One would expect success because yeast extracts have the same chemical composition as whole yeast, and therefore the intact culture provides the same reductive dehalogenation factors as the yeast extract. One would expect success using Brewer's yeast because Keasling et al teach the genus yeast, which one

of ordinary skill in the art recognizes to mean *Saccharomyces* (See, e.g. Merriam-Webster Dictionary definition of "yeast"); therefore all yeast species, including *Saccharomyces*, comprise the desired reductive dehalogenation factors, as no evidence has been provided to show Brewer's yeast has unexpected results over other yeast species (Claims 1, 12 and 13).

Though Keasling et al do not teach specific concentrations or ratios of the carbohydrate source to yeast extract, they clearly indicate that the various proportions and amounts of the lactose, sucrose or glucose and the concentration of yeast extract, or alternatively the concentration of Brewer's yeast, used in the composition are result effective variables, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by Keasling et al. Specifically, Keasling et al teach that the amount of lactose, sucrose, or glucose and yeast is to be altered to perform optimal in situ reductive dehalogenation of organic halides based on the type of carbohydrate used, the organic halides that are to be dehalogenated, the microbial population present in the soil and the presence of other chemicals (See col. 5, ln 11-28). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the concentration of the lactose, sucrose or glucose and Brewer's yeast in the biological stimulant composition to be create appropriate conditions based on the other variables mentioned above; therefore, depending on conditions, the lactose, sucrose, or glucose can comprise anywhere from 40-80% (w/w) or specifically 70% (w/w) and the Brewer's yeast can comprise anywhere from 15-60% (w/w) or specifically 30% (w/w) of the biological stimulant concentration (Claims 2-4, 17 and 18). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that the composition of Keasling et al is not equivalent to or obvious over the present invention because Keasling et al include yeast extract, not whole Brewer's yeast. Applicants

argue Keasling et al provide no suggestion to substitute Brewer's yeast for the yeast extract, and because they, at their experienced level, do not specifically teach Brewer's yeast, it constitutes a specific teaching away from the use of Brewer's yeast. Applicants also argue that whole Brewer's yeast has properties and reaction capabilities, particularly related to the biodegradation rate, not present in yeast extract; thus submitting Brewer's yeast and yeast extract are not functionally equivalent. Applicants further argue that Keasling et al do not teach how to prepare a whole Brewer's yeast preparation, or how to optimize the concentrations of the carbohydrate sources or the yeast. Applicants further argue that the use of whole Brewer's yeast slows the reductive dehalogenation process, which is repugnant to the method of Keasling et al, who desire to expedite the rate of reductive dehalogenation. Therefore applicants argue that, because Keasling et al wish to expedite the rate of reductive dehalogenation, they specifically teach away from the use of whole Brewer's yeast, as it prolongs the reductive dehalogenation process. Additionally, applicants argue that one would not expect successfully substituting whole Brewer's yeast for the yeast extracts of Keasling et al, specifically because Keasling et al desires an expedited dehalogenation process. Finally, applicant presents arguments related to the skill level of Keasling et al and provide results of their own search results.

In response to applicant's arguments regarding the use of yeast extracts by Keasling et al, it is noted that Keasling et al does not use whole Brewer's yeast, as in the current application, but uses yeast extract. Additionally, while Keasling et al provides several different sources of 'nutrient extracts' it is noted that they only teach extracts, not whole cells. However, the fact that Keasling et al does not specifically state that whole Brewer's yeast can be used does not prevent one of ordinary skill in the art from making the obvious substitution of whole yeast for yeast extracts. The rationale or motivation to modify or combine teachings of the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art based on established scientific principles, see MPEP

§ 2144. Therefore, though Keasling et al do not expressly suggest using whole Brewer's yeast, one of ordinary skill in the art would recognize that yeast extract comes from whole yeast; thus in the invention of Keasling et al, one of ordinary skill in the art would recognize whole yeast would provide the same deghalogenating compounds and properties as well as nutrient components as yeast extract. While whole yeast and yeast extract are known to have different properties, applicants have provided no substantive evidence regarding differences in ability to effect reductive dehalogenation. In submitting evidence asserted to establish unobvious results, there is a burden on an applicant to indicate how the examples asserted to represent the claimed invention are considered to relate to the examples intended to represent the prior art and, particularly, to indicate how those latter examples do represent the closest prior art. See *In re Borkowski*, 595 F.2d 713, 184 USPQ 29 (CCPA 1974); *In re Goodman*, 339 F.2d 228, 144 USPQ 30 (CCPA 1964). The evidence relied upon should also be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter "as a class." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971); *In re Hostettler*, 429 F.2d 464, 166 USPQ 558 (CCPA 1970). See, also, *In re Lindner*, 457 F.2d 506, 173 USPQ 356 (CCPA 1972). It should also be established that the differences in the results are in fact unexpected and unobvious and of both statistical and practical significance. *In re Merck*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Klosak*, 455 F2d 1077, 173 UAPQ 14 (CCPA 1972); *In re D'Ancicco*, 429 F.2d 1244, 169 USPQ 303 (CCPA 1971). *Ex parte Gelles*, 22 USPQ2d 1318 (BPAI 1992). Additionally, as for motivation, one of ordinary skill in the art would recognize that use of whole yeast preparations would reduce a step in the preparation of the composition, as use of whole yeasts eliminates the need to lyse and extract the cells, thus saving time and money. Regarding Keasling et al teaching away from the use of whole Brewer's yeast, merely because they do not mention Brewer's yeast as an embodiment, it is noted that a reference merely not teaching every limitation does not constitute a teaching away by that reference. See *In re Grasselli* 713 F.2d 731, 741,

218 USPQ 769, 777 (Fed. Cir. 1983). Though Keasling et al teach the yeast extract can be sterilized by irradiation, and applicant submits this *may* negatively affect whole yeast, it is noted that such purification and sterilization is not required by Keasling et al, rather crude extracts can be used in Keasling et al's composition (See Keasling et al, col. 4, ln 61-67).

In response to applicant's arguments that Keasling et al do not teach how to prepare a whole yeast preparation, or how to optimize the concentrations, it is pointed out that whole yeast preparations, including Brewer's yeast, are commercially available, no further preparation is required. Regarding the optimization of concentration of yeast to be used in the composition of Keasling et al, it would be well within the purview of one skilled in the art to determine the optimal working concentration of yeast through routine experimentation. Though applicant has provided no substantive evidence showing that the claimed concentrations impart any unexpected advantages or results to the claimed composition, the concentration of the carbohydrate source, and the concentration of the yeast are all result effective variables that directly effect the rate and degree of reductive dehalogenation, and thus would be routinely optimized by one of ordinary skill in the art. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The motivation to determine such optimal ranges is based in the normal desire of scientists or artisans to improve upon what is already generally known, See *Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382.* Additionally, it is noted that the specification provides no teachings or criteria for the optimized concentrations, or benefits which are achieved when the components are within the optimized range; therefore, there is no substantial evidence that the claimed ranges provide any specific benefits over any broad concentration range.

In response to applicant's arguments that using whole yeast would slow the degradation time of yeast, thereby increasing the duration of the dehalogenation process, which is opposite the desire of

Keasling et al, the examiner notes that applicants are making a comparison between the degradation time and reductive dehalogenation-effectiveness of whole yeast and that of yeast extract with no substantive evidentiary showing. In submitting evidence asserted to establish unobvious results, there is a burden on an applicant to indicate how the examples asserted to represent the claimed invention are considered to relate to the examples intended to represent the prior art and, particularly, to indicate how those latter examples do represent the closest prior art. (See citations above). The evidence relied upon should also be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter "as a class." It should also be established that the differences in the results are in fact unexpected and unobvious and of both statistical and practical significance. In the instant case applicant has provided no evidence or examples using either whole yeast or yeast extract, much less comparing the two. Thus this argument is considered merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. In response to applicant's argument that the different degradation times of yeast and yeast extract function to teach away from the use of whole yeast in the invention of Keasling et al, as above, there is no evidence that yeast extracts are substantially different in degradation time and reductive dehalogenation effectiveness than whole yeast, thus one cannot use this argument to support a 'teaching away' argument. Additionally, even if it was shown that whole yeast did have a substantially different degradation time that substantially affected the reductive dehalogenation process time, one would still expect success using whole yeast in the invention of Keasling et al, as opposed to the assertion of applicant, one would just not achieve the expedited rate desired by Keasling et al.

In response to applicant's arguments regarding the skill level of Keasling et al and their search results, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The searches performed by applicant are

acknowledged; however, they are not persuasive. Applicant is invited to review the search histories, available in the application file, executed by the examiner.

Claims 5-11 and 14-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Keasling et al (US Patent 6,150,157), in view of Hince (US 2002/0090697 A1).

Keasling et al teach a biological stimulant composition for the reductive dehalogenation of organic halides in contaminated groundwater comprising a carbohydrate and a reductive dehalogenation factor in the form of a nutrient extract (See col. 2, ln 52-65). The carbohydrate can be lactose, sucrose or glucose (which applicant refers to as dextrose) (See col. 4, ln 9-22). The reductive dehalogenation factor can be yeast extracts (See col. 4, ln 40-67).

Though Keasling et al teach using yeast extracts, and not whole Brewer's yeast, as in the current application, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use whole yeast cultures instead of yeast extracts in order to reduce processing steps and costs. Also, the various concentrations and ratios of carbohydrate source to yeast would have been routinely optimized by one of ordinary skill in the art. See teachings above.

Keasling et al do not include vegetable oil or fatty acids in their biological stimulant composition, nor does their biological stimulant composition have a portion with a reduced aqueous solubility. However, Hince teaches a similar solid-chemical composition for the bioremediation of contaminated soil that does include both vegetable oil and fatty acids.

Hince teaches the fatty acids, which are included in salt form, promote the growth of a more diverse range of microorganisms in the contaminated soil (See pg. 5, paragraph 0039). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to include fatty acids in the composition of Keasling et al in order to promote growth of a wider range of anaerobic

microorganisms that are endogenous or exogenously added to the contaminated soil to which the composition of Keasling et al is added (Claims 5, 6, 7, and 14). One of ordinary skill in the art would have been motivated to promote the growth of a wide consortia of microorganisms in the contaminated soil to which the composition of Keasling et al is to be added, because Keasling et al teach that complex cultures of microorganisms are needed to reductively dehalogenate contaminated soil (See Keasling et al, col. 2, ln 52-65). One would have expected success because Hince teaches inclusion of fatty acids in a similar bioremediation composition promotes the growth of diverse microorganisms.

Additionally Hince includes insoluble polymers, that coat a portion of the composition so as to reduce aqueous solubility, causing the coated portion to biodegrade slowly, thereby sustaining release of the substances over time (See Hince, pg 5-6, paragraph 0042-0043). Though Hince does not specifically teach vegetable oils as one of the preferred insoluble materials, he does teach the inclusion of vegetable oil as a lubricant; it will be obvious to one of ordinary skill in the art that the vegetable oil can dually function as an insoluble substrate coating for reducing solubility of the composition (See Hince, pg. 7, paragraph 0052).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to also include vegetable oil in the composition of Keasling et al, in order to coat a portion of the lactose, glucose (dextrose), or sucrose and Brewer's yeast composition in vegetable oil so as to reduce the aqueous solubility of the portion (Claims 8-11, 15, and 16). One would have been motivated to coat a portion of the composition of Keasling et al with vegetable oil in order to decrease the aqueous solubility of that portion, thereby sustaining release of the biological stimulant over time. One would have expected success because the vegetable oil-coated particles will eventually be solubilized and available for reductive dehalogenation in the contaminated soil, and the vegetable oil will not further contaminate the soil.

Therefore the invention as a whole, comprising the biological stimulant composition of Keasling et al modified to include both fatty acids and fatty acids, as taught by Hince, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants state the arguments discussed above over Keasling et al are also applicable for this rejection. Applicants further argues that the vegetable oils of Hince are included as a lubricant to aid in insertion of the solid granules, briquettes, pellets, tablets, and capsules of Hince; they are not used to slow lactose dissolution in a liquid dispersion, as in the present application. Additionally applicant argues that because Hince does not teach coating the particles with the vegetable oil Hince effectively teaches away from coating the sugar particles with vegetable oil. Finally applicant argues that the inclusion of fatty acids to the composition of Keasling et al would not result in applicant's invention; applicant further states that simply because all of the elements of an invention are separately known does not mean that their combination is not patentable.

In response to applicant's arguments regarding the teachings of Keasling et al, it is recognized that Keasling et al do not teach using Brewer's yeast, however, for the reasons stated above, it is maintained that it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute whole Brewer's yeast for yeast extract used by Keasling et al.

In response to applicant's argument that neither Keasling et al nor Hince teach using vegetable oils to coat the sugar particles to delay dissolution in a liquid dispersion, but rather Hince uses the vegetable oil as a lubricant for the solid composition, it is noted that these features of the present invention (liquid dispersion, vegetable oils must delay dissolution of sugars) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Cir. 1993). Whereas the present invention is directed to a liquid dispersion, wherein the vegetable oils delay dissolution of the sugars, Hince teaches the inclusion of vegetable oils; though they are included for a different purpose, they are still taught as part of the composition of the prior art. The present claims are directed to the composition, per se, not to the method of making it or using it; therefore the reason for the inclusion of vegetable oil does not carry patentable weight as the prior art renders the present invention obvious.

Additionally, with regards to applicant's arguments that Hince teaches away from coating the sugar particles with vegetable oil, simply because Hince does not teach coating the sugar particles with vegetable oil, they do not teach or suggest negative results when the vegetable oil contacts the sugars. A reference merely not teaching every limitation does not constitute teaching away by that reference. See *In re Grasselli* 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983).

Finally, with regards to the combination of the components found in Keasling et al and Hince, it is noted that both compositions are intended for reductive dehalogenation of chlorinated aliphatic hydrocarbons (CAH). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the above instantly claimed compositions of Keasling et al and Hince to create a biological stimulate for the purpose of reductive dehalogenation of CAH-contaminated waters and soils. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of ingredients, *In re Sussman,* 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEONB. LANKFORD, JR.
PRIMARY EXAMINER